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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 03/19/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/704,235

Applicant(s)

BHULLAR ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Response to Amendment

1. Applicant's amendment of January 08, 2003 does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed January 06, 2003 have been fully considered but they are not persuasive. Independent claims 1 and 13 have been amended to require that at least a portion of the unsealed portion of the generally flat bottom side of the cover lies upon the reagent. However, this limitation does not patentably distinguish over the prior art applied in the rejections because "generally flat" appears to just mean mostly parallel planar surfaces and "upon" appears to just mean "above" or "over," rather than direct surface contact.

Applicant cites Figure 2 as showing a generally flat cover plate. As seen in the figure the top surface of the cover plate comprises two parallel surfaces having a slight offset. In fact, no irregularities are shown or suggested in any of Applicant's figures. All of the figures show a symmetrical cover plate having a smooth top surface and a smooth bottom surface. Figures 1-5, for example, show only a symmetrical cover with a smooth top surface and a smooth bottom surface having a concave surface. Indeed, page 12, lines 8-11, which is part of the description on how to make Applicant's device, teaches applying a "hot iron (not shown) of appropriate desirable channel shape and size" upon the cover apparently to form a channel in the cover. This further suggests that Applicant's "generally flat" cover plate is not unlike those of the prior art applied in the rejections. Additionally, Applicant should note that the sensors of Charlton et al., Hodges et al., Uenoyama et al., and Ikeda et al. would be expected to be small thin sensors as

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they are disposable sensors requiring only a drop of sample. Uenoyama et al., for example, teach that their sensor is only 0.2 to 2 mm thick (col. 5, ll. 16-20). Thus, the raised flat portion of the cover which forms the unsealed portion of the cover will be only slightly offset from the sealed flat portion of the cover; that is, the cover is generally flat.

Applicant has cited Figure 5 as support for having the generally flat bottom side of the cover lie upon the reagent, but this figure appears to only show the generally flat bottom side of the cover above or over the reagent, which is assumed to be the unlabeled layer above electrodes 80. No disclosure of direct contact between the unsealed bottom surface of the cover and the reagent has been found.

With respect to the rejections of claims based on Charlton et al. Applicant should note the similarity between the concave bottom surface of the cover in Applicant's Figure 4 and the concave bottom surface of the cover in Charlton et al.'s Figure 1.

With respect to the rejections of claims based on Hodges et al. the examiner assumes that Applicant meant to say that layer 13 is not coupled to layer 4 (layer 14 actually includes layer 13. See Figure 14.). Here Applicant appears to limit "coupled" to directly attached. However, there is no showing of why "coupled" should be so narrowly construed. Applicant himself states that layer 13 is coupled to layer 1, but is not layer 1 also coupled to layer 14 and thus layer 13 coupled to layer 14? One with ordinary skill in the art would consider layer 3 coupled to layer 4 through the spacer 1 and adhesive layers 3. Although not in direct contact layer 3 is coupled to layer 4 – if layer 3 is moved then layer 4 is also moved.

With respect to the rejections of claims based on Bhullar et al., Applicant states that the cover (14) does not cooperate with the substrate to define a channel extending across the reagent.

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The examiner respectfully disagrees. The cover (14) cooperates to further define the channel by enclosing the channel, thus providing a channel with four sides instead of three, and by providing obstructions (30), which project into the channel and will alter flow through the channel.

*Status of the Objections and Rejections Applied in and Pending Since
the Office Action of September 05, 2002*

3. The objection to the drawings is withdrawn.
4. The double patenting objection to claims 13 and 16 is withdrawn.
5. The rejection of claims 7, 20, and 21 under 35 U.S.C. 112, second paragraph, is withdrawn.
6. All prior art rejections are withdrawn. The rejections of claims 1-9 based on Charlton et al., Hodges et al., Uenoyama et al., Bhullar et al. (US 6,631,719 B1), and Bhullar (EP 1098000 A2) have been restated in light of Applicant's amendment

Claim Rejections - 35 USC § 112

7. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Independent claims 1 and 13 have been amended to require that at least a portion of the unsealed portion of the generally flat bottom side of the cover lies upon the reagent. Applicant's cited support (page 3 of the amendment) does not explicitly or implicitly support this amendment. In fact, Figure 5 appears to teach away from having the generally flat bottom side of the cover lying upon the reagent as there is a space between the generally flat bottom side of the cover and the unlabeled layer, which is presumably the reagent layer, above the electrodes (80).

8. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicant has amended independent claim 20 to require "that at least a portion of the thermoset adhesive is positioned on the reagent." No support has been found for this limitation. Page 1, lines 33-34 of the specification only teaches placing adhesive on the bottom surface of the cover. From this statement alone one with ordinary skill in the art would

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believe that just the portion of the bottom surface that will form the sealed portion of the cover is covered with adhesive. Page 3, lines 3-8 and page 4, lines 6-15 do not mention adhesive.

Page 12, lines 8-14 teaches heating the adhesive adjacent to the unsealed portion to form a sealed portion. No mention is made of reagent in this passage. The description of Figure 3 on page 4, line 16 – page 5, line 9 only mentions that adhesive may be optionally present. The description of Figure 5 on page 5, lines 9-19 does not mention adhesive. The description of Figure 9 on page 13, line 32 – page 14, line 5 only mentions that the cover may be sealed to the substrate with adhesive.

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1-3, 9, 10, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Charlton et al. (US 5,759,364).

Addressing Claim 1, Charlton et al. teach a biosensor comprising
a substrate (element 36 in Figure 1);
a reagent positioned on the substrate (element 44 in Figure 1); and
a cover (element 46 in Figure 1) including a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces) being coupled to the substrate to define a sealed portion

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and an unsealed portion, at least a portion of the unsealed portion of the generally flat bottom side lying upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5) and cooperating with the substrate to define a channel across the reaction region (inherent from concave portion, 48, of the cover).

Addressing Claims 2 and 3, for the channel extending as claimed note opening 50 in relation to the channel in Figure 1.

Addressing Claim 9, for electrodes as claimed note electrodes 39 and 40 in Figure 1.

Addressing Claim 10, as seen in Figure 1 opening 50 is spaced apart from electrodes 39 and 40.

Addressing Claim 12, adhesive as claimed is disclosed in col. 3, ll. 16-35, especially ll. 29-35.

Addressing Claim 13, Charlton et al. teach a biosensor comprising
a substrate (element 36 in Figure 1);
a reagent positioned on the substrate (element 44 in Figure 1); and
a cover (element 46 in Figure 1) having a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces), and an opening (element 50 in Figure 1) extending

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between the top and bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat bottom side lying upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5) and cooperating with the substrate to define a channel across the reaction region (inherent from concave portion, 48, of the cover).

Addressing Claim 14, a U-shaped interior as claimed may be disconnected from Figure 1.

Addressing Claim 15, for electrodes as claimed not electrodes 39 and 40 in Figure 1.

11. Claims 1-9, 12, 13, and 16-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hodges et al. (US 6,174,420 B1).

Addressing Claim 1, Hodges et al. teach a biosensor comprising
a substrate (bottom element 13 in Figure 15);
a reagent positioned on the substrate (col. 4, ll. 56-65); and
a cover (top element 13 in Figure 15) including a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces) being coupled to the substrate (top element 13 is coupled to bottom element 13 through spacers 1, middle element 13, and adhesive layers 3) to define a sealed portion and an unsealed portion (the sealed portion is the portion of top element 13 coupled to top element 1 through top adhesive layer 3), at least a portion of the unsealed portion of the generally flat bottom side lying upon the reagent (i.e., above or over the reagent as

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in Applicant's Figure 5. This limitation is implied by Figures 12 and 15 and col. 4, ll. 56-65 since reagent is placed in reaction cell, which is covered by the unsealed portion of top element 13) and cooperating with the substrate to define a channel across the reaction region (as seen in Figures 12 and 15 notches 16 cooperated with reaction cell 11 to provide a channel across the reaction region. Also note that sample enters the reaction cell by capillary action (col. 4, ll. 38-42)).

Addressing Claims 2-5 and 16, for a channel extending as claimed note openings 16 in relation to the channel in Figure 12.

Addressing Claim 6, the openings (elements 16 in Figure 12) are disrupted concave surfaces since they do not each have a smooth curvature, but instead have sharply joined edges.

Addressing Claim 7, two openings 16 may be seen in Figure 12.

Addressing Claims 8 and 19, as seen in Figure 12 the channel expands and then converges from the first opening toward the second opening.

Addressing Claim 9, for electrodes as claimed consider electrodes 13 in Figure 15.

Addressing Claim 12, for adhesive as claimed note layers 3 in Figure 15 and col. 4, ll. 26-37.

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Addressing Claim 13, Hodges et al. teach a biosensor comprising a substrate (bottom element 13 in Figure 15); a reagent positioned on the substrate (col. 4, ll. 56-65); and a cover (top element 13 in Figure 15) including a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces), and an opening (openings 16 in Figure 12) extending between the top and bottom sides, the bottom side being coupled to the substrate (top element 13 is coupled to bottom element 13 through spacers 1, middle element 13, and adhesive layers 3) to define a sealed portion and an unsealed portion (the sealed portion is the portion of top element 13 coupled to top element 1 through top adhesive layer 3), at least a portion of the unsealed portion of the generally flat bottom side lying upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5. This limitation is implied by Figures 12 and 15 and col. 4, ll. 56-65 since reagent is placed in the reaction cell, which is covered by the unsealed portion of top element 13) and cooperating with the substrate to define a channel across the reaction region (as seen in Figures 12 and 15 notches 16 cooperated with reaction cell 11 to provide a channel across the reaction region. Also note that sample enters the reaction cell by capillary action (col. 4, ll. 38-42)).

Addressing Claim 17, for edges intersecting the openings as claimed see Figure 12.

Addressing Claim 18, for notches as claimed note openings 16, which include notches, in Figure 12.

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12. Claims 1-3, 9, 10, and 12-15 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Uenoyama et al. (US 6,125,292).

Addressing Claim 1, Uenoyama et al. teach a biosensor comprising
a substrate (element 4 in Figure 1C);
a reagent positioned on the substrate (col. 4, ll. 59-65); and
a cover (element 5 in Figure 1C) including a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces. Note that the thickness of the sensor is only 0.2 to 2 mm (col. 5, ll. 16-20)) being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat bottom side lying upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5. This limitation may be seen in Figure 1C of Uenoyama et al. Note that reagent is not shown on the electrodes, but is disclosed (col. 4, ll. 59-65)) and cooperating with the substrate to define a channel across the reaction region (element 1 in Figure 1C).

Addressing Claims 2 and 3, for a channel extending as claimed note opening 8 in relation to the channel in Figure 1C.

Addressing Claim 9, for electrodes as claimed note electrodes 2 and 3 in Figure 1C.

Addressing Claim 10, as seen in Figure 1C opening 8 is spaced apart from electrodes 2 and 3.

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Addressing Claim 12, adhesive as claimed may be found in col. 4, ll. 54-59.

Addressing Claim 13, Uenoyama et al. teach a biosensor comprising
a substrate (element 4 in Figure 1C);
a reagent positioned on the substrate (col. 4, ll. 59-65); and
a cover (element 5 in Figure 1C) including a top side and a generally flat bottom side
(i.e., having mostly parallel planar surfaces. Note that the thickness of the sensor is only 0.2 to 2
mm (col. 5, ll. 16-20)), and an opening (opening 8 in Figure 1C) extending between the top and
bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an
unsealed portion, at least a portion of the unsealed portion of the generally flat bottom side lying
upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5. This may be seen in
Figure 1C. Note that reagent is not shown on the electrodes, but is disclosed (col. 4, ll. 59-65))
and cooperating with the substrate to define a channel across the reaction region (element 1 in
Figure 1C).

Addressing Claim 14, a U-shaped interior as claimed may be discerned from Figure 1A.

Addressing Claim 15, for electrodes as claimed note electrodes 2 and 3 in Figure 1C.

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 1 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,631,719 B1).

Addressing Claim 1, Bhullar et al. teach a biosensor comprising
a substrate (element 12 in Figures 1 and 2);
a reaction area (element 20 in Figures 1 and 2); and
a cover (element 14 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat bottom side lying upon the reaction area and cooperating with the substrate to define a channel across the reaction area.

Although not shown in the figures Bhullar et al. disclose that reagent can be in the reaction area because Bhullar et al. disclose that “[a] suitable dry reagent can be situated in the reaction region.” See col. 2, ll. 58-59; col. 5, ll. 11-29; and Claim 9. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because as taught by Bhullar et al., with a reagent analytes of interest, such as blood sugar, can be detected. See col. 5, ll. 11-13. Having the cover lying upon the reagent (i.e., above or over the reagent as in Applicant’s Figure 5) is suggested by Figure 1 of Bhullar et al., which shows the cover above the reaction area.

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Addressing Claim 9, electrodes as claimed are implied by Claim 11 and col. 5, ll. 37-39, which discloses having electrochemical detecting apparatus in the reaction region.

Addressing Claim 10, as seen in Figures 1 and 2 the openings 21 are above the reaction region where the electrodes would be located.

Addressing Claim 11, Bhullar et al. do not mention the height of the channel being less than 10 microns, although a height of 100 microns or less is taught (col. 2, ll. 27-30). Barring evidence to the contrary, such as unexpected results, having the channel height less than 10 μm is a design choice. In particular, it is the biosensor taught by Bhullar et al. scaled down in size to better accommodate a smaller sample volume.

15. Claims 2, 3, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,631,719 B1) as applied to Claims 1 and 9-11 above, and further in view of Uenoyama et al. (US 6,125,292) and Bhullar (EP 1098000 A2).

Addressing Claims 2 and 3, although Bhullar et al. teach having the channel extend between an opening adjacent the cover and the reagent (note vent 21 in Figures 1 and 2), Bhullar et al. do not disclose having the opening in the cover. However, having an opening in the cover, such as a vent in the cover of a biosensor, was known at the time of the invention as shown, for example, by Figure 1C (note element 8) of Uenoyama et al. and Figure 14 of Bhullar

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EP 1098000 A2 (note element 52). Barring evidence to the contrary, such as unexpected results, the location of the vent is a design choice, with the primary concern being avoiding sample fluid leaking through the vent.

Addressing Claim 7, it should first be noted that the Examiner has assumed that this claim was meant to depend from Claim 2 because Claim 2 provides antecedent basis for a second opening in the cover. Two openings are disclosed in Figure 2 of Bhullar et al. As argued in the rejection of Claim 2, above, having vents in the cover instead of the walls of a biosensor was a known design variant at the time of invention.

Addressing Claim 13, Bhullar et al. teach a biosensor comprising
a substrate (element 12 in Figures 1 and 2);
a reaction area (element 20 in Figures 1 and 2); and
a cover (element 14 in Figure 1) having a top side and a generally flat bottom side, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat bottom side cooperating with the substrate to define a channel extending up to the reaction area.

Although not shown in the figures Bhullar et al. disclose that reagent can be in the reaction area because Bhullar et al. disclose that “[a] suitable dry reagent can be situated in the reaction region.” See col. 2, ll. 58-59; col. 5, ll. 11-29; and Claim 9. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because as taught by Bhullar et al., with a reagent analytes of interest, such as blood

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sugar, can be detected. See col. 5, ll. 11-13. Having the cover lying upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5) is suggested by Figure 1 of Bhullar et al., which shows the cover above the reaction area.

Also, although Bhullar et al. teach having the channel extend between an opening adjacent the cover and the reagent (note vent 21 in Figures 1 and 2), Bhullar et al. do not disclose having the opening between the top and bottom sides of the cover. However, having an opening through the cover, such as a vent in the cover of a biosensor, was known at the time of the invention as shown, for example, by Figure 1C (note element 8) of Uenoyama et al. and Figure 14 of Bhullar EP 1098000 A2 (note element 52). Barring evidence to the contrary, such as unexpected results, the location of the vent is a design choice, with the primary concern being avoiding sample fluid from leaking through the vent.

16. Claims 1-3 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar (EP 1098000 A2).

Addressing Claim 1, Bhullar (EP 1098000 A2) teach a biosensor comprising
a substrate (improperly labeled as element 28 in Figure 12; according to col. 6, ll. 21-23 "28" refers to the electrode set);

a cover (element 32 in Figure 12) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the sensing region (col. 4, ll. 21-26 and Figure 12).

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Bhullar (EP 1098000 A2) does not directly mention an a reagent in the reaction region; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because Bhullar (EP 1098000 A2) discloses "reagent is optional, and may be used to provide electrochemical probes for specific analytes" See col. 8, ll. 39-47. As taught by Bhullar et al., with a reagent analytes of interest, such as blood glucose, can be detected. See col. 8, ll. 47-56. Having the cover lying upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5) is suggested by Figure 14 of Bhullar et al., which shows the cover above the reaction area.

Addressing Claims 2 and 3, for a channel extending as claimed note opening 52 in relation to the channel in Figure 14 of Bhullar (EP 1098000 A2).

Addressing Claim 9, electrodes as claimed are shown in Figure 12 of Bhullar (EP 1098000 A2).

Addressing Claim 10, as seen in Figure 14 of Bhullar (EP 1098000 A2) opening 52 is spaced apart from electrodes 44.

Addressing Claim 11, Bhullar (EP 1098000 A2) does not mention the height to the channel, although a height in microns is implied because they teach that the channel is a capillary channel (col. 6, ll. 44-46). Barring evidence to the contrary, such as unexpected results, having

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the channel height less than 10 μm is a design choice. In particular, it is the biosensor taught by Bhullar (EP 1098000 A2) scaled down in size to better accommodate a smaller sample volume.

Addressing Claim 12, using an adhesive is taught in col. 6, ll. 27-29.

Addressing Claim 13, Bhullar (EP 1098000 A2) teach a biosensor comprising a substrate (improperly labeled as element 28 in Figure 12; according to col. 6, ll. 21-23 “28” refers to the electrode set);

a cover (element 32 in Figure 12) including a top side and a generally flat bottom side, and an opening (opening 52 in Figure 14 of Bhullar (EP 1098000 A2)) extending between the top and bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, the unsealed portion cooperating with the substrate to define a channel across the sensing region (col. 4, ll. 21-26 and Figure 12).

Bhullar (EP 1098000 A2) does not directly mention an a reagent in the reaction region; however, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because Bhullar (EP 1098000 A2) discloses “reagent is optional, and may be used to provide electrochemical probes for specific analytes” See col. 8, ll. 39-47. As taught by Bhullar et al., with a reagent analytes of interest, such as blood glucose, can be detected. See col. 8, ll. 47-56. Having the cover lying upon the reagent (i.e., above or over the reagent as in Applicant’s Figure 5) is suggested by Figure 14 of Bhullar et al., which shows the cover above the reaction area.

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17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al. (US 5,759,364).

Charlton et al. teach a biosensor comprising
a substrate (element 36 in Figure 1);
a reagent positioned on the substrate (element 44 in Figure 1); and
a cover (element 46 in Figure 1) including a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces) being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat bottom side lying upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5) and cooperating with the substrate to define a channel across the reaction region (inherent from concave portion, 48, of the cover).

Charlton et al. do not mention the height of the channel although it appears to be less than 10 μm because they state "[t]he typical thickness of the entire structure is 6 μm (col. 3, ll. 3-4). In any event, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have the channel height less than 10 μm because the surrounding elements are 10 μm or less in thickness (col. 3, ll. 10-15) and the channel is a capillary channel (col. 3, ll. 23-26) that can accommodate as little as 7 μl of sample (col. 9, ll. 61-63).

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18. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al.

(US 6,174,420 B1). Hodges et al. teach a biosensor comprising

a substrate (bottom element 13 in Figure 15);

a reagent positioned on the substrate (col. 4, ll. 56-65); and

a cover (top element 13 in Figure 15) including a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces) being coupled to the substrate (top element 13 is coupled to bottom element 13 through spacers 1, middle element 13, and adhesive layers 3) to define a sealed portion and an unsealed portion (the sealed portion is the portion of top element 13 coupled to top element 1 through top adhesive layer 3), at least a portion of the unsealed portion of the generally flat bottom side lying upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5. This limitation is implied by Figures 12 and 15 and col. 4, ll. 56-65 since reagent is placed in reaction cell, which is covered by the unsealed portion of top element 13) and cooperating with the substrate to define a channel across the reaction region (as seen in Figures 12 and 15 notches 16 cooperated with reaction cell 11 to provide a channel across the reaction region. Also note that sample enters the reaction cell by capillary action (col. 4, ll. 38-42)).

Hodges et al. do not mention the height of the channel, although a height in microns is implied because they teach that the channel is a capillary channel (col. 4, ll. 38-44) and that the electrodes, which form the top and bottom surfaces of the channel, are preferably less than 200 microns apart (col. 1, ll. 64-67). Barring evidence to the contrary, such as unexpected results, having the channel height less than 10 μm is a design choice. In particular, it is the biosensor taught by Hodges et al. scaled down in size to better accommodate a smaller sample volume.

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19. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uenoyama et al. (US 6,125,292).

Uenoyama et al. teach a biosensor comprising
a substrate (element 4 in Figure 1C);

a reagent positioned on the substrate (col. 4, ll. 59-65); and

a cover (element 5 in Figure 1C) including a top side and a generally flat bottom side (i.e., having mostly parallel planar surfaces. Note that the thickness of the sensor is only 0.2 to 2 mm (col. 5, ll. 16-20)) being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat bottom side lying upon the reagent (i.e., above or over the reagent as in Applicant's Figure 5. This limitation may be seen in Figure 1C of Uenoyama et al. Note that reagent is not shown on the electrodes, but is disclosed (col. 4, ll. 59-65)) and cooperating with the substrate to define a channel across the reaction region (element 1 in Figure 1C).

20. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,6319,719 B1) in view of Uenoyama et al. (US 6,125,292) in view of Charlton et al. (US 5,759,364).

Bhullar et al. teach a biosensor comprising
a substrate (element 12 in Figures 1 and 2);

a reaction area (element 20 in Figures 1 and 2); and

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a cover (element 14 in Figure 1) including a top side and a generally flat bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat bottom side lying upon the reaction area and cooperating with the substrate to define a channel across the reaction area.

Although not shown in the figures Bhullar et al. disclose that reagent can be in the reaction area because Bhullar et al. disclose that “[a] suitable dry reagent can be situated in the reaction region.” See col. 2, ll. 58-59; col. 5, ll. 11-29; and Claim 9. It would have been obvious to one with ordinary skill in the art at the time the invention was made to have reagent in the reaction area because as taught by Bhullar et al., with a reagent analytes of interest, such as blood sugar, can be detected. See col. 5, ll. 11-13. Having the cover lying upon the reagent (i.e., above or over the reagent as in Applicant’s Figure 5) is suggested by Figure 1 of Bhullar et al., which shows the cover above the reaction area.

Bhullar et al. do not directly mention using adhesive between the cover and substrate, although using an adhesive appears to be implied by col. 5, ll. 7-10, which teaches using a solvent to fix the cover and substrate. In any event, using adhesive to attaché the cover and substrate of a biosensor was a known alternative at the time of the invention, as shown be col. 4, ll. 56-59 in Uenoyama et al. and col. 3, ll. 16-36 in Charlton et al. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use adhesive between the cover and substrate as taught by Uenoyama et al. and Charlton et al. in the invention of Bhullar et al. because as taught by Charlton et al., depending on the composition of the materials used a more leakproof capillary space may result when adhesive is used (col. 3, ll. 32-35). Also, it would have been obvious to one with ordinary skill in the art at the time the invention was made

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to use adhesive if it would be cheaper than other commonly used techniques, such as heat bonding or mechanical coupling, and still provide an adequate result.

Final Rejection

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A, shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

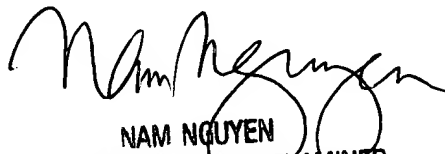
22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Alex Noguerola
March 12, 2003


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